

1 APPARATUS FOR THE ENDOLUMINAL TREATMENT OF  
2 GASTROESOPHAGEAL REFLUX DISEASE (GERD)

3

4 This application is related to co-owned application Serial  
5 Number --/----,---, filed simultaneously herewith, entitled  
6 "Flexible Surgical Clip Applier" (Docket #SYN-039A) the complete  
7 disclosure of which is hereby incorporated by reference herein.

8

9 This application is a continuation-in-part of application  
10 Serial Number 09/931,528, filed August 16, 2001, entitled "Methods  
11 and Apparatus for Delivering a Medical Instrument Over an  
12 Endoscope while the Endoscope is in a Body Lumen", the complete  
13 disclosure of which is hereby incorporated by reference herein.

14

15 This application is also a continuation-in-part of  
16 application Serial Number 09/891,775, filed June 25, 2001,  
17 entitled "Surgical Clip", the complete disclosure of which is  
18 hereby incorporated by reference herein.

19

20 This application also claims the benefit of provisional  
21 application Serial Number 60/292,419, filed May 21, 2001, entitled  
22 "Methods and Apparatus for On-Endoscope Instruments  
23 Having End Effectors and Combinations of On-Endoscope  
24 and Through-Endoscope Instruments".

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1 This application is also a continuation-in-part of  
2 application Serial Number 09/730,911, filed December 6, 2000,  
3 entitled "Methods and Apparatus for the Treatment of Gastric  
4 Ulcers", the complete disclosure of which is hereby incorporated  
5 by reference herein.

## BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention relates to endoscopic surgical instruments. More particularly, the invention relates to flexible instruments for the transoral invagination and fundoplication of the stomach to the esophagus.

## 2. State of the Art

16 Gastroesophageal fundoplication is a procedure for the  
17 treatment of gastroesophageal reflux disease (GERD), a condition  
18 in which gastric acids are regurgitated into the esophagus  
19 resulting in one or more of esophagitis, intractable vomiting,  
20 asthma, and aspiration pneumonia. The fundoplication procedure  
21 involves wrapping the fundus of the stomach around the lower end  
22 of the esophagus and fastening it in place. Traditionally, this  
23 procedure is accomplished via open surgery with the use of sutures  
24 to secure the plicated fundus of the stomach around the esophagus  
25 without penetrating (incising) the stomach. Although traditional

1 fundoplication involves plicating the fundus and the esophagus, as  
2 used herein the term includes plicating the fundus to itself near  
3 the esophagus.

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5 U.S. Patent Number 5,403,326 to Harrison et al. discloses a  
6 method of performing endoscopic fundoplication using surgical  
7 staples or two-part surgical fasteners. The procedure disclosed  
8 by Harrison et al. involves performing two percutaneous endoscopic  
9 gastrotomies (incisions through the skin into the stomach) and the  
10 installation of two ports through which a stapler, an endoscope,  
11 and an esophageal manipulator (invagination device) are inserted.  
12 Under view of the endoscope, the esophageal manipulator is used to  
13 pull the interior of the esophagus into the stomach. When the  
14 esophagus is in position, with the fundus of the stomach plicated,  
15 the stapler is moved into position around the lower end of the  
16 esophagus and the plicated fundus is stapled to the esophagus.  
17 The process is repeated at different axial and rotary positions  
18 until the desired fundoplication is achieved. While, the  
19 procedure disclosed by Harrison et al. is a vast improvement over  
20 open surgery, it is still relatively invasive requiring two  
21 incisions through the stomach.

22

23 U.S. Patent Number 5,571,116 to Bolanos et al. discloses a  
24 non-invasive treatment of gastroesophageal reflux disease which  
25 utilizes a remotely operable invagination device and a remotely

1 operable surgical stapler, both of which are inserted transorally  
2 through the esophagus. According to the methods disclosed by  
3 Bolanos et al., the invagination device is inserted first and is  
4 used to clamp the gastroesophageal junction. The device is then  
5 moved distally, pulling the clamped gastroesophageal junction into  
6 the stomach, thereby invaginating the junction and involuting the  
7 surrounding fundic wall. The stapler is then inserted transorally  
8 and delivered to the invaginated junction where it is used to  
9 staple the fundic wall.

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Bolanos et al. disclose several different invagination devices and several different staplers. Generally, each of the staplers disclosed by Bolanos et al. has an elongate body and a spring biased anvil which is rotatable approximately 15 degrees away from the body in order to locate the invaginated gastroesophageal junction between the body and the anvil. The body contains a staple cartridge holding a plurality of staples, and a staple firing knife. Each of the invagination devices disclosed by Bolanos et al. has a jaw member which is rotatable at least 45 degrees and in some cases more than 90 degrees to an open position for grasping the gastroesophageal junction. One of the chief disadvantages of the methods and apparatus disclosed by Bolanos et al. is that the stapler and the invagination device must both be present in the esophagus at the same time. With some of the embodiments disclosed, the presence of both instruments is

1 significantly challenged by the size of the esophagus. In  
2 addition, the actuating mechanism of the device disclosed by  
3 Bolanos et al. is awkward. In particular, the stapler anvil is  
4 biased to the open position, and it is not clear whether or not  
5 the stapler anvil can be locked in a closed position without  
6 continuously holding down a lever. In addition, it appears that  
7 the staple firing trigger can be inadvertently operated before the  
8 anvil is in the closed position. This would result in inadvertent  
9 ejection of staples into the stomach or the esophagus of the  
10 patient.

11

12 U.S. Patent Number 6,086,600 to Kortenbach discloses an  
13 endoscopic surgical instrument including a flexible tube, a  
14 grasping and fastening end effector coupled to the distal end of  
15 the tube, and a manual actuator coupled to the proximal end of the  
16 tube. The manual actuator is coupled to the end effector by a  
17 plurality of flexible cables which extend through the tube. The  
18 tube contains a lumen for receiving a manipulable endoscope and  
19 the end effector includes a passage for the distal end of the  
20 endoscope. The end effector has a store for a plurality of male  
21 fastener parts, a store for a plurality of female fastener parts,  
22 a rotatable grasper, a rotatable fastener head for aligning a  
23 female fastener part and a male fastener part with tissues  
24 therebetween, and a firing member for pressing a male fastener  
25 part through tissues grasped by the grasper and into a female

1 fastener part. According to a stated preferred embodiment, the  
2 overall diameters of the flexible tube and the end effector (when  
3 rotated to the open position) do not exceed approximately 20 mm so  
4 that the instrument may be delivered transorally to the fundus of  
5 the stomach.

6

7 While transoral invagination and fundoplication apparatus and  
8 procedures have improved over the years, it is still difficult to  
9 deliver and manipulate the necessary apparatus transorally. The  
10 primary reason for the difficulty is that the overall diameter, or  
11 more accurately the cross sectional area, of the equipment is too  
12 large. Notwithstanding Kortenbach's reference to 20mm, most of  
13 the equipment in use today is at least 24mm in diameter.

14 Moreover, even if the equipment could be reduced to 20mm in  
15 diameter ( $314 \text{ mm}^2$  cross sectional area), it would still be  
16 difficult to manipulate. Those skilled in the art will appreciate  
17 that larger instruments are less pliable and that the invagination  
18 and fundoplication procedure requires that the instruments turn  
19 nearly 180 degrees. Moreover, it will be appreciated that large  
20 instruments obscure the endoscopic view of the surgical site.

21

22 Still other issues which need to be addressed in this  
23 procedure include the need to suitably grasp the fundus before  
24 plication so that all layers of the fundus are plicated.

1 Preferably, plication damages the fundus so that adhesion occurs  
2 during healing.

3

4 3. Co-owned Technology

5 Previously incorporated application Serial Number 09/730,911,  
6 filed December 6, 2000, entitled "Methods and Apparatus for the  
7 Treatment of Gastric Ulcers", discloses a surgical tool which is  
8 delivered to a surgical site over an endoscope rather than through  
9 the working lumen of an endoscope.

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12 Co-owned provisional application Serial Number 60/292,419,  
13 filed May 21, 2001, entitled "Methods and Apparatus for On-  
14 Endoscope Instruments Having End Effectors and Combinations of On-  
15 Endoscope and Through-Endoscope Instruments", discloses many tools  
16 and procedures including an on-scope grasper assembly having  
17 grasping jaws, and a through-scope clip applier having jaws  
18 adapted to close about tissue and apply a clip over and/or through  
19 the tissue. In operation, the grasper jaws may grab and hold  
20 tissue, e.g., the fundus of the stomach or esophageal tissue,  
21 while the jaws of the clip applier surround a portion of the  
22 tissue held by the grasper jaws and apply a clip thereover.

23

24 Previously incorporated application Serial Number 09/891,775,  
25 filed June 25, 2001, entitled "Surgical Clip", discloses a  
surgical clip having a U-shaped configuration with first and

1 second arms, and a bridge portion therebetween. The first arm is  
2 provided with a tip preferably having a catch, and the second arm  
3 extends into a deformable retainer having a tissue-piercing end  
4 and preferably also a hook. During application, tissue is  
5 clamped, and the clip is forced over the clamped tissue and the  
6 retainer of the second arm is bent and may be pierced through the  
7 tissue. The retainer is toward and around or adjacent the tip of  
8 the first arm preferably until the hook is engaged about the catch  
9 to secure the clip to the tissue and prevent the clip and tissue  
10 from separating. The clip is provided with structure that  
11 facilitates the stacking of a plurality of clips in a clip chamber  
12 of a clip applier.

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14 Previously incorporated application Serial Number 09/931,528,  
15 filed August 16, 2001, entitled "Methods and Apparatus for  
16 Delivering a Medical Instrument Over an Endoscope while the  
17 Endoscope is in a Body Lumen", discloses methods and apparatus for  
18 delivering a medical instrument over the exterior of an endoscope  
19 while the endoscope is installed in the patient's body in order to  
20 allow the use of instruments which are too large to fit through  
21 the lumina of an endoscope.

22

23 The previously incorporated simultaneously filed application  
24 entitled "Flexible Surgical Clip Applier", discloses a surgical  
25 clip applier having a pair of clip applying jaws at the distal end

1 of an outer coil, a set of pull wires extending through the outer  
2 coil and coupled to the jaws, and a push wire extending through  
3 the outer coil. A clip chamber is provided in the distal end of  
4 the coil. A clip pusher is provided at a distal end of the push  
5 wire, and adapted to advance a clip into the jaws. The jaws  
6 include clamping surfaces which operate to compress tissue between  
7 the jaws when the jaws are closed, channels in which a distalmost  
8 clip rides when the jaws are closed and the pusher is advanced  
9 thereby causing the distalmost clip to be pushed over the tissue,  
10 and distal anvil portions which operate to bend a portion of the  
11 distalmost clip to facilitate its retention on the clamped tissue.  
12 The clip applier is capable of providing a pushing force far in  
13 excess of a perceived possible maximum of the 200 grams (0.44 lbs)  
14 published in the art. One embodiment of the device of the  
15 invention provides a pushing force in excess of 2267 grams (5  
16 lbs).

## SUMMARY OF THE INVENTION

20 It is therefore an object of the invention to provide methods  
21 and apparatus for transoral invagination and fundoplication.

23 It is also an object of the invention to provide an apparatus  
24 for transoral invagination and fundoplication which is easy to  
25 manipulate.

1        It is another object of the invention to provide an apparatus  
2    for transoral invagination and fundoplication which has a  
3    relatively small cross-sectional area.

4

5        It is still another object of the invention to provide  
6    methods and apparatus for fundoplication which combine the  
7    relative advantages of staples and two-part fasteners, i.e. the  
8    small size of a staple and the greater integrity of a two-part  
9    fastener.

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11

12       It is yet another object of the invention to provide methods  
13    and apparatus for transoral invagination and fundoplication which  
14    damages tissue such that adhesion occurs during healing.

15

16       In accord with these objects which will be discussed in  
17    detail below, the methods of the invention include delivering a  
18    grasper, a clip applier, and an endoscope transorally to the site  
19    of fundoplication; grasping the fundus with the grasper (or  
20    similar device, e.g. corkscrew) and pulling it into the jaws of  
21    the clip applier; closing the jaws of the clip applier over the  
22    fundus and applying a clip to the fundus. The method is repeated  
23    at different locations until the desired fundoplication is  
24    achieved. The apparatus of the invention includes a clip applier  
25    having sharp toothed jaws for grasping and damaging the fundus  
prior to applying the clip. The clip applier has an overall

1 diameter of less than 7mm and may be delivered through a 7mm  
2 sleeve which attaches to a 12mm endoscope having a lumen through  
3 which the grasper is delivered. The overall cross-sectional area  
4 of the apparatus is therefore approximately 152 mm<sup>2</sup> as compared to  
5 the 314mm<sup>2</sup> of the prior art devices. Alternatively, the clip  
6 applier and the grasper may be delivered through an endoscope  
7 having two 6mm lumina.

8

9 According to a presently preferred embodiment, the clip  
10 applier jaws are coupled to a pull wire via a linkage which  
11 increases the mechanical advantage and thus permits greater  
12 grasping force.

13

14 A plurality of clip designs are provided. Some embodiments  
15 include a pair of arms coupled by a bridge and a single locking  
16 retainer. Other embodiments include dual parallel coiled  
17 retainers. According to one embodiment, the clip has two  
18 detachable retainers which are installed in the fundus and the  
19 clip arms and bridge are removed.

20

21 Additional objects and advantages of the invention will  
22 become apparent to those skilled in the art upon reference to the  
23 detailed description taken in conjunction with the provided  
24 figures.

1                   BRIEF DESCRIPTION OF THE DRAWINGS  
23                   Figure 1 is a side elevational view of a clip applier  
4 according to the invention;  
56                   Figure 2 is a side elevational view of a first embodiment of  
7 the distal end of the clip applier with the jaws in the closed  
8 position;  
910                  Figure 3 is a side elevational view of a first embodiment of  
11 the distal end of the clip applier with the jaws in the open  
12 position;  
1314                  Figure 4 is a broken isometric view of a first embodiment of  
15 the distal end of the clip applier with one jaw removed;  
1617                  Figure 5 is a broken isometric view of a second embodiment of  
18 the distal end of the clip applier with a clip of the type shown  
19 in Figures 19 and 20;  
2021                  Figure 6 is an isometric view of a single jaw of the second  
22 embodiment of the distal end of the clip applier;  
2324                  Figure 7 is a proximal end view of the jaw of Figure 6;  
25

1       Figure 8 is a proximal end view of the two jaws of a second  
2 embodiment of the distal end of the clip applier in the closed  
3 position with the lower jaw shaded for clarity;

4

5       Figure 9 is a broken isometric view of a third embodiment of  
6 the distal end of the clip applier suitable for use with a clip of  
7 the type shown in Figures 17 and 18 or 24;

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9       Figures 10-14 are schematic views illustrating a method  
10 according to the invention;

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12       Figure 15 is a diagram illustrating the comparative cross-  
13 section of the instruments used in the method illustrated in  
14 Figures 5-10 and a typical prior art instrument;

15

16       Figure 16 is a cross-sectional view of a dual lumen endoscope  
17 which can be used in performing the methods of the invention;

18

19       Figure 17 is a side elevational view of a first embodiment of  
20 a clip according to the invention prior to application;

21

22       Figure 18 is a side elevational view of the clip of Figure 17  
23 after application;

24

1       Figure 19 is a side elevational view of a second embodiment  
2 of a clip according to the invention prior to application;

3

4       Figure 20 is a side elevational view of the clip of Figure 19  
5 after application;

6

7       Figure 21 is a side elevational view of a third embodiment of  
8 a clip according to the invention prior to assembly;

9

10       Figure 22 is a side elevational view of the clip of Figure 21  
11 assembled prior to application;

12

13       Figure 23 is a side elevational view of the applied portion  
14 of the clip of Figures 17 and 18; and

15

16       Figure 24 is a view similar to Figure 23 of an alternate  
17 third embodiment of the applied portion of a clip according to the  
18 invention.

1           DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS  
2

3           Referring now to Figure 1, a clip applier 10 according to the  
4           invention generally includes a flexible wound outer coil 12 having  
5           a proximal end 14 and a distal end 16. An end effector assembly  
6           18 is coupled to the distal end 16 of the coil 12 and an actuator  
7           assembly 20 is coupled to the proximal end 14 of the coil 12. A  
8           plurality of pull/push wires 58, 60 (shown and described below  
9           with reference to Figures 2-4) extend through the coil 12 and  
10          couple the end effector assembly 18 to the actuator assembly 20.  
11          The clip applier 10 is similar to the clip applier described in  
12          detail in previously incorporated co-owned application Serial  
13          Number --/----,---, entitled "Flexible Surgical Clip Applier",  
14          filed simultaneously herewith. However, in this application, the  
15          end effector assembly 18 is designed specifically for  
16          fundoplication using a clip significantly larger than that used in  
17          the clip applier of the aforesaid co-owned application.

18

19          Figures 2-4 illustrate the details of the end effector  
20          assembly 18 according to a first embodiment of the invention. The  
21          end effector assembly 18 includes a pair of jaws 22, 24 which are  
22          rotatably coupled to a clevis 26. In particular, the clevis 26  
23          has a central channel 28 (seen best in Figure 4) which is defined  
24          by clevis arms 30, 32. Although the term "clevis" is used because  
25          of its general acceptance in the art of endoscopic instruments,

1 the "clevis" 26 is preferably covered on top and bottom so that  
2 the only exit from the channel 28 is at the distal end. The jaw  
3 22 is rotatably coupled to the clevis arm 30 by an axle 34 and the  
4 jaw 24 is rotatably coupled to the clevis arm 32 by an axle 36.  
5 The axles 34 and 36 are dimensioned such that they do not  
6 significantly obscure the channel 28.

7

8 The jaws 22, 24 are substantially identical. Each jaw 22, 24  
9 includes a proximal tang 38, 40, a mounting bore 42, 44, a distal  
10 hook shaped anvil 46, 48 and a plurality of medial teeth 50, 52.  
11 As seen best in Figure 4, the medial teeth 50, 52 are arranged on  
12 one side of the jaw and a short wall 51, 53 is arranged on the  
13 opposite side of the jaw to define a groove (or guiding channel)  
14 54, 56. The grooves 54, 56 meet the anvils 46, 48 each of which  
15 which has a helical surface. The interior (proximal) helical  
16 surfaces of the anvils act to bend the clip retainers as described  
17 below with reference to Figures 19-24.

18

19 The proximal tang 38, 40 of each jaw is coupled to a  
20 respective pull/push wire 58, 60 via two links 62, 64 and 66, 68.  
21 The links 62, 66 are substantially L-shaped and are rotatably  
22 coupled near their elbow to the clevis arms 30, 32 by axles 70, 72  
23 which do not significantly obscure the channel 28 between the  
24 clevis arms. One end of the link 62, 66 is coupled to the  
25 pull/push wire 58, 60 and the other end of the link 62, 66 is

1 rotatably coupled to one end of the link 64, 68. The other end of  
2 the link 64, 68 is rotatably coupled to the tang 38, 40. The  
3 combined coupling of each jaw 22, 24 to each pull/push wire 58, 60  
4 forms a linkage which amplifies the force from the pull/push wires  
5 to the jaws. In particular, as the jaws close, the mechanical  
6 advantage increases.

7

8 The proximal ends of the pull/push wires 58, 60 are coupled  
9 to the actuator assembly (20 in Figure 1) as described in  
10 previously incorporated co-owned application Serial Number --/---  
11 ,---, entitled "Flexible Surgical Clip Applier", filed  
12 simultaneously herewith.

13

14 A clip pusher (not shown) disposed in the interior of the  
15 coil is coupled to a push wire (not shown) which is coupled to the  
16 actuator assembly as described in previously incorporated co-owned  
17 application Serial Number --/---,---, entitled "Flexible Surgical  
18 Clip Applier", filed simultaneously herewith. Unlike the  
19 previously incorporated co-owned application, the jaws of the  
20 instant clip applier are significantly longer and designed for use  
21 with clips approximately 17-20mm long (after the clip is applied)  
22 as compared to the 5-7mm clips shown in the previously  
23 incorporated co-owned application.

24

1       Turning now to Figures 5-8, a second embodiment of the jaws  
2 22', 24' is illustrated. The jaws 22', 24' are substantially  
3 identical to each other and are designed for use with any of the  
4 clips illustrated in Figures 19-24. Each jaw 22', 24' includes a  
5 proximal tang 38', 40', a mounting bore 42', 44', a distal hook  
6 shaped anvil 46', 48' and a plurality of medial teeth 50', 52'.  
7 The medial teeth 50', 52' are arranged on one side of the jaw and  
8 a short wall 51', 53' is arranged on the opposite side of the jaw  
9 to define a groove (or guiding channel) 54', 56'. The grooves  
10 54', 56' meet the interior surfaces of the anvils 46', 48' which  
11 curve about a single axis. The interior surfaces of the anvils  
12 act to bend the clip retainers as described below with reference  
13 to Figures 19-24 and as shown by the clip 310 in Figure 5.  
14 According to this embodiment, as seen best in Figures 6-8, the  
15 guiding channels 54', 56' and the anvils 46', 48' are angled  
16 relative to the vertical axis of the jaw 22', 24'. This angle  
17 causes the clip to twist as it is pushed through the jaws so that  
18 the ends of the clip are offset as shown in Figure 5, for example.  
19 According to the presently preferred embodiment, the guiding  
20 channels 54', 56' and the anvils 46', 48' are angled approximately  
21 22° relative to the vertical axis of the jaw 22', 24'. According  
22 to a method of the invention, clips for use with this embodiment  
23 of the jaws are prebent in the bridge area to facilitate movement  
24 through the angled channels.

25

1 Referring now to Figure 9, a third embodiment of the jaws  
2 22", 24" is illustrated. The jaws 22", 24" are not identical to  
3 each other and are designed for use with clips of the type  
4 illustrated in Figures 17-18. Each jaw 22", 24" includes a  
5 proximal tang 38", 40" and a mounting bore 42", 44". One jaw 22"  
6 terminates with two spaced apart distal hooks 46", 47" and has two  
7 rows of medial teeth 50". The other jaw 24" terminates with a  
8 single distal hook shaped anvil 48" and has two rows of medial  
9 teeth 52". The medial teeth 50", 52" are arranged on both sides  
10 of the jaw and a groove (or guiding channel) 54", 56" lies between  
11 the rows of teeth. The groove 54" terminates with an undercut  
12 well (not shown) as described in co-owned Serial Number --/----,--,  
13 whereas the groove 56" continues on to the interior of the anvil  
14 48" which has a surface which curves about a single axis. Those  
15 skilled in the art will appreciate that when the jaws are closed,  
16 the anvil 48" will reside between the hooks 46" and 47" and the  
17 teeth 50" will be interleaved with the teeth 52". The interior  
18 surface of the anvil 48" bends the clip retainer as described  
19 below with reference to Figures 17-18 and as shown and described  
20 in previously incorporated co-owned applications Serial Number  
21 09/891,775, and Serial Number --/----,---.

22

23 Turning now to Figures 10-14, a method of using the clip  
24 applier of the invention is illustrated in context with an  
25 existing endoscope 100 having a single lumen through which a small

1 grasper 102 is supplied and an external working channel 104 which  
2 is attached to the scope 100 and through which the clip applier is  
3 delivered. The external working channel 104 is preferably one of  
4 the type described in previously incorporated application Serial  
5 Number 09/931,528, filed August 16, 2001, entitled "Methods and  
6 Apparatus for Delivering a Medical Instrument Over an Endoscope  
7 while the Endoscope is in a Body Lumen".

8

9 According to a method of the invention, after the endoscope  
10 assembly is delivered transorally to the procedural site, as shown  
11 in Figure 10, the fundus is grasped by the graspers and pulled in  
12 between the open jaws of the clip applier. The jaws of the clip  
13 applier are then closed onto the invaginated fundus as shown in  
14 Figure 11. As the jaws are closed the medial teeth of the jaws  
15 puncture the invaginated fundus as shown in Figures 11 and 12.  
16 When the jaws are completely closed (or closed as much as  
17 possible), they are preferably locked, the grasper is optionally  
18 released, and the clip pusher is activated to push forward a clip  
19 106 as shown in Figure 12 and as described in the previously  
20 incorporated, co-owned, simultaneously filed application and  
21 discussed in detail hereinafter.

22

23 After the clip 106 is applied, the jaws of the clip applier  
24 are opened as shown in Figure 13 and the clip 106 remains in place  
25 and plicates the fundus. Depending on the location of the clip

1 and the nature of the patient's condition, a single clip may be  
2 sufficient. If other clips are deemed desirable by the  
3 practitioner, the clip applier is removed and re-loaded with  
4 another clip. After re-delivering the clip applier, the procedure  
5 may be repeated at another location as shown in Figure 14. Given  
6 the size of the clips of the invention, anywhere from 1-4 clips  
7 will typically be used.

8

9 According to one aspect of the invention, the medial teeth on  
10 the jaws of the clip applier are long enough and sharp enough to  
11 damage the fundus sufficiently such that when the fundus heals  
12 adhesion occurs, binding the plicated fundus to the extent that  
13 the clip may no longer be needed. Thus, preferably, the teeth are  
14 long enough to pierce all layers of the fundus.

15

16

17 From the foregoing, those skilled in the art will appreciate  
18 that the methods of the invention may be performed with different  
19 types of graspers. In particular, alternative grasping devices  
20 such as a "cork screw" grasper can be used in conjunction with the  
21 clip applier of the invention to perform the methods of the  
22 invention.

23

24 It will also be appreciated that the clip applier of the  
25 invention may be attached to an endoscope in other ways as  
described in previously incorporated application Serial Number

1 09/931,528, filed August 16, 2001, entitled "Methods and Apparatus  
2 for Delivering a Medical Instrument Over an Endoscope while the  
3 Endoscope is in a Body Lumen".

4

5 As mentioned above, the clip applier of the invention has an  
6 outside diameter of approximately 6mm. As shown in Figures 10-14,  
7 the clip applier is used in conjunction with an endoscope having  
8 an outside diameter of approximately 12mm. To accommodate the  
9 clip applier, an exterior working channel having an exterior  
10 diameter of approximately 7mm is optionally coupled to the  
11 endoscope as described in the previously incorporated co-owned  
12 applications Serial Numbers 09/931,528 and 60/292,419.

13

14 Figure 15 is a scale representation of the cross-sectional  
15 area of the 12mm endoscope 100 with the attached external 7mm  
16 working channel 104, shown in horizontal shading. The cross  
17 sectional area of a prior art device 108 having an exterior  
18 diameter of approximately 24mm is shown in diagonal shading. From  
19 Figure 15, it will be appreciated that the methods and apparatus  
20 of the invention allow for a substantially smaller device which is  
21 more easily delivered transorally and which is more easily  
22 manipulated. The overall cross-sectional area of the apparatus of  
23 the invention is approximately  $152 \text{ mm}^2$  as compared to the  $314\text{mm}^2$  of  
24 the prior art devices.

25

1       As mentioned, the clip applier of the invention may also be  
2    used with a dual lumen endoscope. Figure 16 is a scale  
3    representation of a dual lumen endoscope 110 having an optical  
4    lumen 112 and two 6mm working lumina 114, 116. As compared to the  
5    device 108 in Figure 15, the endoscope 110 has a substantially  
6    smaller cross-sectional area than the prior art device.

7

8       The clips used by the clip applier of the invention are  
9    substantially longer than the clips described in the previously  
10   incorporated co-owned applications, Serial Number 09/891,775 and  
11   the simultaneously filed application, which are approximately 7mm  
12   in length and adequate for general surgical applications. The  
13   retainer portion of the clips of the present invention are  
14   substantially longer in order to assure that all of the layers of  
15   the fundus are punctured.

16

17       Turning now to Figures 17 and 18, a first embodiment of a  
18   surgical clip 210 according to the invention includes first and  
19   second arms 212, 214, respectively, and a bridge portion 216  
20   therebetween such that the arms and bridge portion are in a  
21   generally U-shaped configuration. The first arm 12 is provided  
22   with an end catch 220, and the second arm 214 extends (or  
23   transitions) into a deformable retainer 222 having a tissue  
24   piercing tip 224 and a plurality of catch engagements, e.g. 226,  
25   228. The arms define an open space 230 between them. The clip

1 210 is preferably made from a unitary piece of titanium, titanium  
2 alloy, stainless steel, tantalum, platinum, other high Z  
3 (substantially radiopaque) materials, nickel-titanium alloy,  
4 martensitic alloy, or plastic, although other suitable  
5 biocompatible materials may be used. The first and second arms  
6 212, 214, as well as the bridge portion 216 are relatively stiff  
7 and not plastically deformable within the limits of force applied  
8 to the arms during use, while the retainer 222 is relatively  
9 easily plastically deformable by the clip applier.

10

11

12 Referring now to Figures 2-4 and 17-18, when the clip 210 is  
13 pushed forward in the clip applier with the jaws 22, 24 of the  
14 clip applier closed, the retainer 222 is bent across the opening  
15 230 between the first and second arms 212, 214 and into engagement  
16 with the end catch 220 of the first arm 212 as shown in Figure 18.  
17 The anvil formed by the grooves on the interior of the hooks 46,  
18 48 of the clip applier jaws guide the bending of the retainer 222  
19 causing it to puncture the fundus and couple to the end catch 220.

20

21

22 The clip 210 shown in Figures 17 and 18 is provided with an  
23 optional bendable barb 232 which provides a secondary stabilizing  
24 fixation point which helps keep the clip from rotating. As the  
25 clip is pushed forward over the fundus, tissue catches the barb  
232 and bends it as shown in Figure 18.

1        The clip 210 is also provided with an ear 233 on the bridge  
2        216. The ear is used by the pushing mechanism (not shown) to  
3        grasp the end of the clip when it is loaded into the clip applier.  
4

5        A second embodiment of a clip 310 according to the invention  
6        is shown in Figures 19 and 20. The clip 310 has two arms 312, 314  
7        connected by a bridge 316. Both arms terminate in retainers 320,  
8        322, each having a sharp end 321, 323. The clip 310 is also  
9        provided with a pair of ears 333, 335 on the bridge 316. The ears  
10      are used by the pushing mechanism (not shown) to grasp the end of  
11      the clip when it is loaded into the clip applier. This embodiment  
12      is intended for use with a clip applier having hooks with interior  
13      grooves which diverge, or which are in parallel planes. With  
14      reference to Figures 2-4 and 15-16, when the clip 310 is pushed  
15      forward, the retainer 320 is bent by the groove inside the hook 46  
16      and the retainer 322 is bent by the groove inside the hook 48 to  
17      the configuration shown in Figure 20. From Figure 20, it will be  
18      appreciated that each retainer punctures the fundus twice  
19      substantially forming a circular fastener. Thus, it will also be  
20      appreciated that the retainers 320, 322 are significantly longer  
21      than the retainer 222 shown in Figures 17 and 18 and preferably  
22      are of a length at least  $\pi$  times the distance between the arms  
23      312, 314. Insofar as the retainers 320, 322 each form a complete  
24      fastener, the function of the arms 312, 314 and the bridge 316 may  
25      be considered redundant.

1       Figures 21-23 illustrate a third embodiment of a clip 410  
2       according to the invention. The clip 410 is similar to the clip  
3       310 (with similar reference numerals increased by 100 referring to  
4       similar parts) except that the retainers 420, 422 are removable  
5       from the arms 412, 414. The arms 412, 414 terminate in female  
6       couplings 413, 415 which receive ends of the retainers 420, 422 in  
7       a slight interference fit. The clip 410 is also provided with a  
8       pair of ears 433, 435 on the bridge 416. The ears are used by the  
9       pushing mechanism (not shown) to grasp the end of the clip when it  
10      is loaded into the clip applier. The clip 410 is applied to the  
11      fundus in substantially the same way as described above with  
12      reference to the clip 310. However, after the retainers 420, 422  
13      are bent by the anvils and the jaws are opened, the clip 410 is  
14      not released from the clip applier and the retainers are separated  
15      from the arms 412, 414. The resulting fastener formed by the  
16      retainers 420, 422 is shown in Figure 23. This is actually two  
17      substantially parallel "b" shaped fasteners. Thus, it may only be  
18      necessary to apply a single retainer as shown in Figure 24, for  
19      example.

20

21       There have been described and illustrated herein several  
22      embodiments of methods and apparatus for the endoluminal treatment  
23      of gastroesophageal reflux disease. While particular embodiments  
24      of the invention have been described, it is not intended that the  
25      invention be limited thereto, as it is intended that the invention

1 be as broad in scope as the art will allow and that the  
2 specification be read likewise. It will therefore be appreciated  
3 by those skilled in the art that yet other modifications could be  
4 made to the provided invention without deviating from its spirit  
5 and scope as so claimed.

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